4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0398]

Eli Lilly and Company, et al.; Withdrawal of Approval of 3 New Drug Applications and 41 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 3 new drug applications and 41 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Table 1.--Requests to Withdraw Approval of Applications

Application No.	Drug	Applicant
NDA 050440	Keflet (cephalexin) Tablets	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 050614	Keftab (cephalexin hydrochloride) Tablets	Do.
NDA 050673	Ceclor CD (cefaclor) Tablets	Do.
ANDA 075457	Famotidine Tablets USP, 20 milligrams (mg) and 40 mg	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26505-4310
ANDA 075559	Butorphanol Tartrate Injection USP, 1 mg/milliliter (mL) and 2 mg/mL	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045
ANDA 075572	Buspirone HCl Tablets USP, 5 mg, 10 mg, and 15 mg	Nesher Pharmaceuticals (USA) LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044
ANDA 075594	Pamidronate Disodium for Injection, 30 mg/vial and 90 mg/vial	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618
ANDA 075609	Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg	Nesher Pharmacueticals (USA) LLC
ANDA 075613	Bupropion HCl Tablets, 75 mg and 100 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038-0446
ANDA 075627	Acyclovir Injection, 50 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 075730	Thiotepa for Injection USP, 15 mg/vial and 30 mg/vial	Do.
ANDA 075793	Famotidine Tablets USP, 20 mg and 40 mg	Sandoz Inc.
ANDA 075847	Oxaprozin Tablets USP, 600 mg	Mylan Pharmaceuticals, Inc.
ANDA 075905	Famotidine Injection, 10 mg/mL	Hospira, Inc.
ANDA 075943	Etodolac Extended-Release Tablets, 400 mg, 500 mg, and 600 mg	Sandoz Inc.
ANDA 075950	Fluvoxamine Maleate Tablets, 50 mg and 100 mg	Mylan Pharmaceuticals, Inc.
ANDA 076018	Amiodarone HCl Injection, 50 mg/mL	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146
ANDA 076042	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg	Mylan Pharmaceuticals, Inc.
ANDA 076044	Potassium Chloride Extended-Release Tablets USP, 20 milliequivalents	Nesher Pharmaceuticals (USA) LLC
ANDA 076088	Amiodarone HCl Injection, 50 mg/mL	Bedford Laboratories
ANDA 076193	Propafenone HCl Tablets, 150 mg, 225 mg, and 300 mg	Nesher Pharmaceuticals (USA) LLC
ANDA 076259	Milrinone Lacate in 5% Dextrose Injection	Baxter Healthcare Corp., 25212 W. Illinois Route 120, Round Lake, IL 60073
ANDA 076299	Amiodarone HCl Injection, 50 mg/mL	Bedford Laboratories
ANDA 076315	Topiramate Tablets, 25 mg, 100 mg, and 200 mg	Barr Laboratories, Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 076372	Brimonidine Tartrate Ophthalmic Solution, 0.2%	Teva Parenteral Medicines, Inc.

Application No.	Drug	Applicant
ANDA 076398	Tamoxifen Citrate Tablets USP, 10 mg and 20 mg	Aegis Pharmaceuticals PLC, c/o GlobePharm Inc., 313 Pine St., Suite 204, Deerfield, IL 60015
ANDA 076424	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg	Pliva Inc., c/o Barr Laboratories Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, U.S. Agent, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 076448	Topiramate Capsules, 15 mg and 25 mg	Barr Laboratories, Inc.
ANDA 076529	Loratadine Syrup (loratadine oral solution USP), 1 mg/mL	Ranbaxy Laboratories Limited, c/o Ranbaxy Inc., U.S., 600 College Rd. East, Princeton, NJ 08540
ANDA 076540	Sertraline HCl Tablets, 25 mg, 50 mg, and 100 mg	Mylan Pharmaceuticals, Inc.
ANDA 076612	Benazepril HCl and Hydrochlorothiazide Tablets, 5 mg/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg	Do.
ANDA 076640	Metoprolol Succinate Extended-Release Tablets, 100 mg and 200 mg	Nesher Pharmaceuticals (USA) LLC
ANDA 076865	Fluticasone Proprionate Cream, 0.05%	Do.
ANDA 076982	Prednisolone Sodium Phosphate Oral Solution USP, 5 mg/5 mL	Do.
ANDA 076992	Ciprofloxacin Injection USP, 10 mg/mL	Bedford Laboratories
ANDA 076993	Ciprofloxacin Injection USP, 10 mg/mL	Do.
ANDA 077074	Lorazepam Injection USP (Preservative-Free), 2 mg/mL and 4 mg/mL	Do.
ANDA 077076	Lorazepam Injection USP, 2 mg/mL and 4 mg/mL, 10 mL per vial	Do.
ANDA 077080	Amlodipine Besylate Tablets, 2.5 mg, 5 mg, and 10 mg	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709
ANDA 077085	Leflunomide Tablets, 10 mg and 20 mg	Sandoz Inc.
ANDA 077311	Hydromorphone HCl Tablets USP, 2 mg, 4 mg, and 8 mg	Nesher Pharmaceuticals (USA) LLC
ANDA 085917	Acetaminophen and Codeine Phosphate Tablets, 30 mg	Sandoz Inc.
ANDA 087423	Acetaminophen and Codeine Phosphate Tablets, 300 mg/60 mg	Do.
ANDA 087433	Acetaminophen and Codeine Phosphate Tablets, 300 mg/15 mg	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective

[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the DATES section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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